

REMARKS

Reconsideration of the claims in view of the above amendments and following remarks is respectfully requested. The amendments are made without disclaimer or prejudice to Applicants' right to claim any subject matter in a continuing application.

1. Status of the Claims

Claims 1-5 and 7-32 stand pending. Claims 1-5, 7, 15-18, 21-27, and 29-32 stand rejected. Claims 3-5, 7, and 23-25 are objected to. Claims 8-14, 19-20, and 28 are withdrawn.

2. Support for the Amendments

Claims 1 and 21 are amended to incorporate the subject matter of claims 2 and 3 and claims 22 and 23, respectively. The amendments do not add subject matter not explicitly recited and supported in the claims as filed. The amendments thus do not add impermissible new matter.

3. Election/Restriction: Request for Rejoinder

Claims 8-14, 19-20, and 28 are withdrawn pursuant to Applicants' election of Group I, claims 1-5, 7, 15-18, 21-27, and 29-32 in the Response filed September 13, 2007. Election was made with traverse on the grounds that the restriction was improper under 37 C.F.R. § 1.475(b)(1), and that the non-elected method claims in any event should be rejoined to the elected claims upon an indication of allowance of claim 1.

The restriction made in the Office Action mailed August 13, 2007, was predicated on the allegation that Kamata *et al.*, *Comp. Biochem. Physiol.* 86: 587-91 (1987) ("Kamata") teaches the special technical feature uniting the claims. Kamata teaches an astaxanthin *diester* that may contain lauric acid (C₁₂), among other fatty acids. The present claims are directed in part to an astaxanthin medium-chain fatty acid *monoester*, wherein the medium-chain fatty acid has 8 to 12 carbon atoms. Kamata does not teach an astaxanthin monoester. Because Kamata does not teach the special technical feature uniting the presently amended claims, the restriction requirement predicated on Kamata should be withdrawn. Accordingly, Applicants request that all the withdrawn claims be rejoined and examined on the merits.

4. Information Disclosure Statements

Applicants note with appreciation the acknowledgement of the Information Disclosure Statements (IDSs) filed July 15, 2005, January 30, 2006, and September 13, 2007. The Office did not consider the references cited on the IDS filed October 20, 2004, because the Office did not receive copies of the cited references from the International Search Authority. As a courtesy, Applicants provide herewith copies of the cited references, the fee required under 37 C.F.R. § 1.97(c), a clean copy of the PTO Form 1449 for the Examiner's signature upon consideration of the listed references, and a copy of the International Search Report issued in PCT/JP03/05443 on August 12, 2003.

5. Objection to the Drawings

The drawings filed October 24, 2004, are objected to because "Figure 1 is not reproducible." Applicants believe that the Office objects to the use of the half-tone background in Figures 1 and 2 (Sheet 1 of the Drawings), which makes the figures hard to read once they are photocopied. Applicants herewith provide new copies of Figures 1 and 2, labeled "Replacement Sheet" in the top margin, that do not contain half-tone backgrounds. The objection thus may be withdrawn.

6. Certified Priority Documents

Applicants note with appreciation the indication that the certified priority documents have been received in the instant application.

7. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 3, 4, 7, and 23-25 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants traverse the rejections.

[1] Claims 3 and 4 are rejected as allegedly unclearly referring to one of several medium-chain fatty acids recited in claim 2. The present amendment incorporates the subject matter of claims 2 and 3 into claim 1. Claim 1 is directed to an astaxanthin medium-chain fatty acid monoester, where the medium-chain fatty acid has 8 to 12 carbon atoms. Claim 4 further recites that the medium-chain fatty acid has an even number of carbon atoms, i.e., it is a C₈, C₁₀, or C₁₂ fatty acid. The claims are definite, and the rejection should be withdrawn.

AMENDMENTS TO THE DRAWINGS

Please replace sheet 1 of the Drawings with two new sheets, marked in the top margin as "Replacement Sheet" and attached hereto. The sheets together include all of the figures appearing on sheet 1 of the Drawings. The changes to the Drawings are explained in detail in item 5 of the Remarks section of the amendment paper.

[2] Claim 7 is rejected for omitting the conjunction “or.” The rejection is moot in view of the present amendment.

[3] Claims 23-25 are rejected as allegedly lacking an antecedent basis for “the medium-chain fatty acid.” Claim 23 is canceled. Claims 24 and 25 depend from claim 21. Claim 21 recites “an astaxanthin medium-chain fatty acid ester.” The molecule contains an astaxanthin moiety ester-linked to a medium-chain fatty acid moiety. The latter moiety provides an antecedent basis for “the medium-chain fatty acid,” and the rejection thus should be withdrawn.

8. Rejections Under 35 U.S.C. § 102(b)

Claims 1-5, 7, 18, 21-26, 27, and 32 stand rejected under 35 U.S.C. § 102(b) as being allegedly clearly anticipated by U.S. Patent No. 6,709,688 B1 (“Breivik”). Applicants traverse the rejection as it applies to the amended claims. To clarify the record, Breivik is available as prior art under 35 U.S.C. § 102(e), not § 102(b). The corresponding published PCT application, WO 00/62625, however, is available under 35 U.S.C. § 102(b).

Astaxanthin has two hydroxyl moieties that can form esters with fatty acids. *See* Specification, Formula (1). Astaxanthin thus is capable of forming a monoester and a diester with a fatty acid. Breivik teaches a C₁₀ fatty acid diester of astaxanthin (*e.g.*, Breivik, col. 3, lines 47-49), but not fatty acid monoesters of astaxanthin. The amended claims are directed to a fatty acid monoester of astaxanthin. All the elements of the claims are not taught by Breivik, and the rejection accordingly should be withdrawn.

9. Rejection of the Claims Under 35 U.S.C. § 103(a)

[1] Claims 7 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Breivik and Kamata. Applicants traverse the rejection.

Claims 7 and 27 are directed to an astaxanthin octanoic acid (C₈) monoester or a composition comprising the same. The Office admits that neither Breivik nor Kamata teach an astaxanthin octanoic acid monoester. The Office alleges that “since it was known that an astaxanthin octanoic acid diester exists, it is within the purview of an artisan of ordinary skill that an astaxanthin octanoic acid monoester existed.” Based on this allegation, the Office concludes that the claims would have been obvious. Office Action, page 8.

Whether a claim is obvious is based on an objective analysis of the scope and content of the prior art, the differences between the prior art and each element of the claimed

invention, the level of skill in the pertinent art, and secondary considerations supporting a conclusion of obviousness or non-obviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 15-17 (1966); *see also* M.P.E.P. § 804. The Office's objective analysis of obviousness should be made explicit. *See KSR Int'l Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). The factual inquiry whether to combine references must be based on objective evidence of record. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002) ("This precedent has been reinforced in myriad decisions, and cannot be dispensed with."). In short, the factual question of motivation cannot be resolved on the basis of subjective belief. *Lee*, 277 F.3d at 1343-44.

With particular regard to the determination of obviousness of chemical compounds, the Federal Circuit recently held: "[The] test for *prima facie* obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*." *Takeda Chem. Indus. Ltd. v. Alphapharm Pty. Ltd.*, 83 U.S.P.Q.2d 1169, 1174 (Fed. Cir. 2007). The appropriate test is whether "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness." *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1901 (*en banc*) (Fed. Cir. 1990). That is, in addition to structural similarity between the compounds, a *prima facie* case of obviousness requires a showing of "adequate support in the prior art" for the change in structure. *In re Grabiak*, 769 F.2d 729, 731-32, 226 U.S.P.Q. 870, 872 (Fed. Cir. 1985). The prior art must suggest the specific molecular modifications necessary to achieve the claimed invention. *Takeda*, 83 U.S.P.Q.2d at 1174 (citing cases).

In the present case, the cited art teaches an astaxanthin diester having C₁₀ fatty acid moieties. The Office alleges that the cited art would have suggested smaller fatty acid chains linked to an astaxanthin diester. Office Action, page 8. The Office, however, provides no reason or motivation based on the cited art or otherwise to make an astaxanthin monoester. *See Dillon*, 16 U.S.P.Q.2d at 1901. In particular, the Office provides no support in the cited art for the proposed change in structure. *See Grabiak*, 769 F.2d at 731-32; *Takeda*, 83 U.S.P.Q.2d at 1174.

Without providing a reason or evidence, the Office alleges that “it is within the purview [i.e., range of competence] of an artisan of ordinary skill that an astaxanthin octanoic acid monoester existed.” Office Action, page 8. In the context of obviousness, the issue is not whether it would have been within the range of competence of the artisan to know that an astaxanthin octanoic acid monoester existed. Instead, the issue is whether there would have been a reason or motivation based on the cited art or otherwise *to make* the specific molecular modifications necessary to achieve the claimed astaxanthin monoester. *See Takeda*, 83 U.S.P.Q.2d at 1174. The present rejection cannot be sustained on a merely conclusory statement that the claimed invention would have been within the purview of the artisan. *See KSR*, 82 U.S.P.Q.2d at 1396; *Kahn*, 441 F.3d at 988. The Office does not state a proper *prima facie* case of obviousness, and, for this reason alone, the rejection should be withdrawn.

Further, the Office has not taken into account the superior properties and advantages of the claimed compounds in alleging obviousness. Figures 1 and 2, for example, depict the accumulation of orally administered astaxanthin mono- and di-esterified with caprylic acid in blood plasma and liver, respectively. *See, e.g.*, Specification, page 4, line 23, through page 5, line 10; page 56, line 19, through page 57, line 15. As can be seen from the Figures, both the astaxanthin mono- and di-esters of caprylic acid accumulate in blood plasma and liver to a higher degree than commercially available Astax9000H. As can also be seen, the astaxanthin monoester demonstrates an advantageously superior accumulation in blood plasma and liver compared to the astaxanthin diester. The cited art does not suggest these advantageous properties of the presently claimed astaxanthin monoesters.

[2] Claims 27 and 15-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Breivik and Kamata in view of U.S. Patent No. 5,965,795 (“Hirschberg”). Applicants traverse the rejection.

The Office cites Hirschberg for its teaching of a composition comprising an astaxanthin that is useful in food, as a food additive, or in a cosmetic. Hirschberg does not teach or suggest an astaxanthin medium-chain fatty acid monoester. Hirschberg thus does cure the deficiencies in the combination of Breivik and Kamata proposed above. Because the combined teachings of Breivik, Kamata, and Hirschberg do not teach or suggest the subject matter of the present claims, the Office has not made a proper *prima facie* case of obviousness. The rejection accordingly should be withdrawn.

CONCLUSION

In conclusion, this is believed to be in full response to the outstanding restriction requirement. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience. Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to charge or credit Deposit Account No. 50-0573.

Respectfully submitted,

Date: March 10, 2008

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